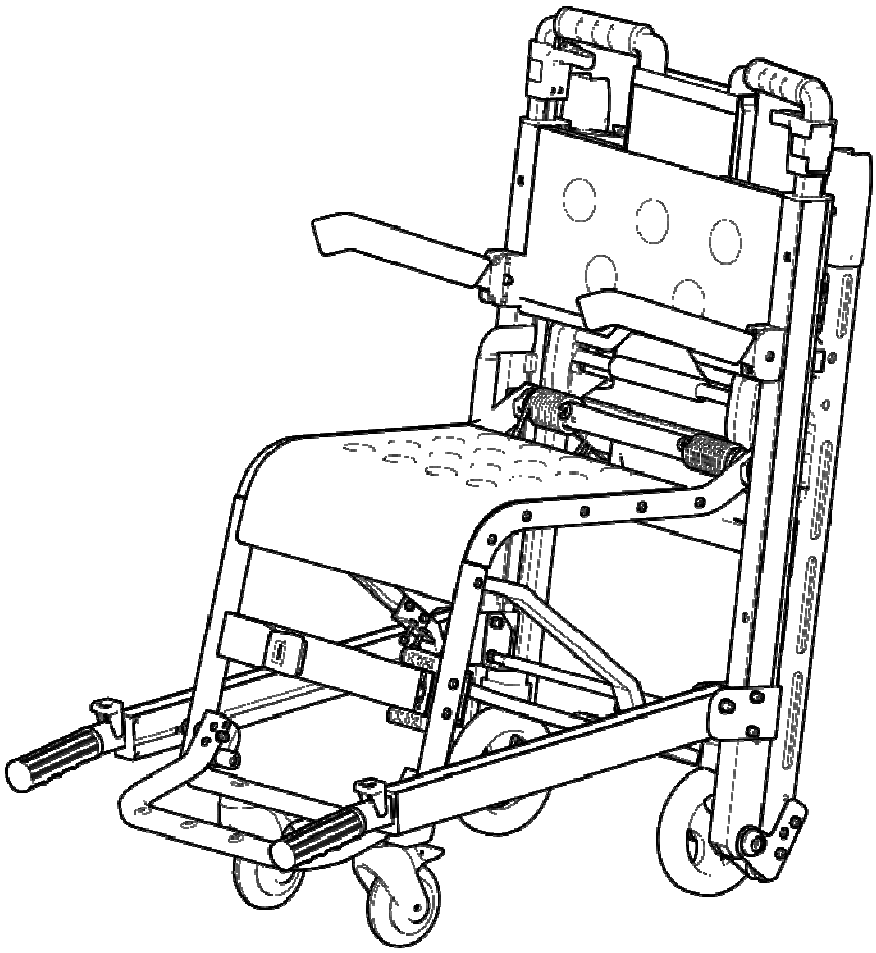
User's Manual

EVA

Transport and evacuation chair



CE This appliance conforms with the Directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH

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Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction manual

The instruction and maintenance manual must be kept together with the product, for the whole life of the device, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 Symbols used

Symbol	Meaning
	General or specific warning
	See instructions for use
SN	Serial number
REF	Product code
CE	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail service@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) shown on the label applied on the box or on the device.

1.5 Demolition

When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the manufacturer, the product, CE mark, serial number (SN), information and safety data. In case of damage or removal, request a duplicate to the manufacturer, or the warranty will become invalid, since the device can no longer be tracked and considered safe.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or manufacturer if requested.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not the device received, inform the manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.

- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the manufacturer in this user's manual.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
  In addition, both public and private operators are obliged to inform the manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users of any medical device.

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying a reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in the user's manual.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or manufacturer if requested.
- Use only accessories/spare parts that are original or approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Always respect the maximum capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.

- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Do not wash the device in the washing machine.
- Do not use drying machines.
- Lubrication must be carried out after cleaning and complete drying.
- The device is equipped with security seals, if they are removed the manufacturer will no longer recognize the product warranty and will accept no responsibility for the improper functioning or damages caused by the device itself.
- Follow the procedures approved by the Emergency Medical Services for the immobilization of the patient.
- Follow the procedures approved by the Emergency Medical Services for the positioning and transport of the patient.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn, frayed or excessively worn out.
- Make sure, before lifting, that the operators have a firm grip on the device.
- Avoid pulling the device on rough surfaces.
- Do not lift by crane or other mechanical lifts.
- The device is a chair for patients transport and cannot be used as a stationing device.
- First practice with an empty chair in order to get used to the way in which the chair manoeuvres.
- For the use of the device, at least two operators in suitable physical conditions are needed; they must therefore have strength, balance, coordination, and common sense and must be trained on the correct functioning of the Spencer device.
- For techniques for loading particularly heavy patients, for rescue operations on steep ground or in unusual circumstances, it is recommended the presence of more operators (not just two as required under standard conditions).
- The maximum weight sustained by each rescuer must comply with requirements prescribed by the law of the Country, concerning Health and Safety at Work.
- Before each use, check the integrity of the belts and their hooks, as specified in the user's manual. In case of malfunction or damage that may compromise the function and safety of the device, patient or operator, it is necessary to replace the belts.
- Make sure the belts are properly fastened to the chair's frame.
- Always immobilize the patient, using the straps supplied by the manufacturer; lack of immobilization may cause serious damage.
- Do not operate in case the weight has not been distributed correctly.
- Do not alter or modify the chair arbitrarily to make it fit into the ambulance: the modification may cause unforeseeable functioning and damages to the patient and operators. In any case the warranty will be lost. The manufacturer will no more considered responsible.
- Pay a lot of attention to possible obstacles (water, ice, debris, etc.) on the route of the chair, because they could cause loss of balance for the operator and compromise the proper functioning of the device. If you can not set the path free from obstacles, choose an alternative path.
- For high gradients, the device must be raised, taking care to grasp the transport handles.
- Condensation, water, ice and accumulations of dust can affect the correct operation of the device, making it unpredictable and causing a sudden alteration of the weight that operators have to carry.
- Water, ice, debris on stairs can cause loss of balance of the operator and compromise the proper functioning of the device. To avoid injury clean the route from obstructions or choose an alternate route.
- The chairs are certified for use with dedicated Spencer fastening systems, it is therefore forbidden the use of fasteners not approved by the manufacturer. Fastening systems that have not been approved may alter the structural and functional characteristics of the stretchers.
- Replace the wheels with original parts, in case of failure to stop the device.
- An unlocked chair may close during use, causing injury to the patient and/or the operator. Before use ensure that the chair is always locked in the closed position.
- To avoid injury, before lifting the chair, always check that the lifting handles are securely locked.
- It 's better not to use the chair in case of suspected cervical traumas, spinal damages or fractures.
- To avoid any risk for the safety of the patient and the rescuer, during transport on stairs at least two operators must be present. In the event that more people are needed to ensure safe operation on the chair, please consult the appropriate section of this manual to locate the right position that every operator must take.
- Use the brakes only when transferring the patient or when there is no one on the chair. If the chair is moved with locking devices inserted, it might tip over causing injury to the patient or the operator and/or damages to the equipment.
- The brakes are used only to avoid the empty chair to move when unsupervised and as an aid during patient transfer. The brake may not provide sufficient resistance on all surfaces or under load.

- Never use a brake on a chair with severely worn wheels. If the wheel appears to have a diameter less than 150 mm, this could affect the sealing capability of the locking device and thereby cause possible injury to the patient or the operator and damage to the device or other equipment.
- The swivelling wheels are not suitable for all surfaces, so be careful.

2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

2.4 Physical requirements of the operators

Eva Spencer chair is a device destined to professional use only. The rescue operators must have the following minimum requirements:

- physical capacity for operating the device
- be able to seize the device firmly with both hands
- have strong back, arms and legs for lifting, pushing and pulling the device
- have a good muscular coordination
- must have been correctly trained to use the medical device

Every operator must be trained in efficient and safe patient transport.

Patient loading procedures for extremely heavy patients, operations in rough terrain and in particular situations more operators may be needed (not only two as in normal conditions).

The capacities of the operators must be considered before determining their roles in the employment of the device.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

EVA Spencer chair is a device designed to move and to transport a patient in a sitting position to the ambulance. The device cannot be used to transport the patient inside the ambulance. It is not expected that the patient can intervene on the device.

3.2 Main components (see figure 1 and 2)

n°	Description of component	Materials
1	Fastener for head support	Pvc
2	Head support	Pvc
3	Backrest	Pvc or abs
4	Transport handle	Pvc
5	Seat	Pvc or abs
6	Strap for legs	Nylon and polypropylene
7	Release button for front handles	Nylon
8	Reclining footrest	Aluminium
9	Rear handle	Rubber
10	Slide	Aluminium, nylon, pvc
11	Release button for slide	Nylon
12	Adjusting system for slide	Nylon and aluminium
13	Release button for main handle	Nylon
14	Release button for rear handles	Nylon
15	Command the brake functioning	Aluminium
16	Pedal for automatic closure	Aluminium and nylon
17	Rear wheels	Polyethylene
18	Main handle	Aluminium
19	Armrests	Aluminium and expanded polyethylene
20	Front handles	Rubber
21	Front wheels	Pvc and nylon

Not every component shown in the chart is present in all the versions of EVA evacuation chair.

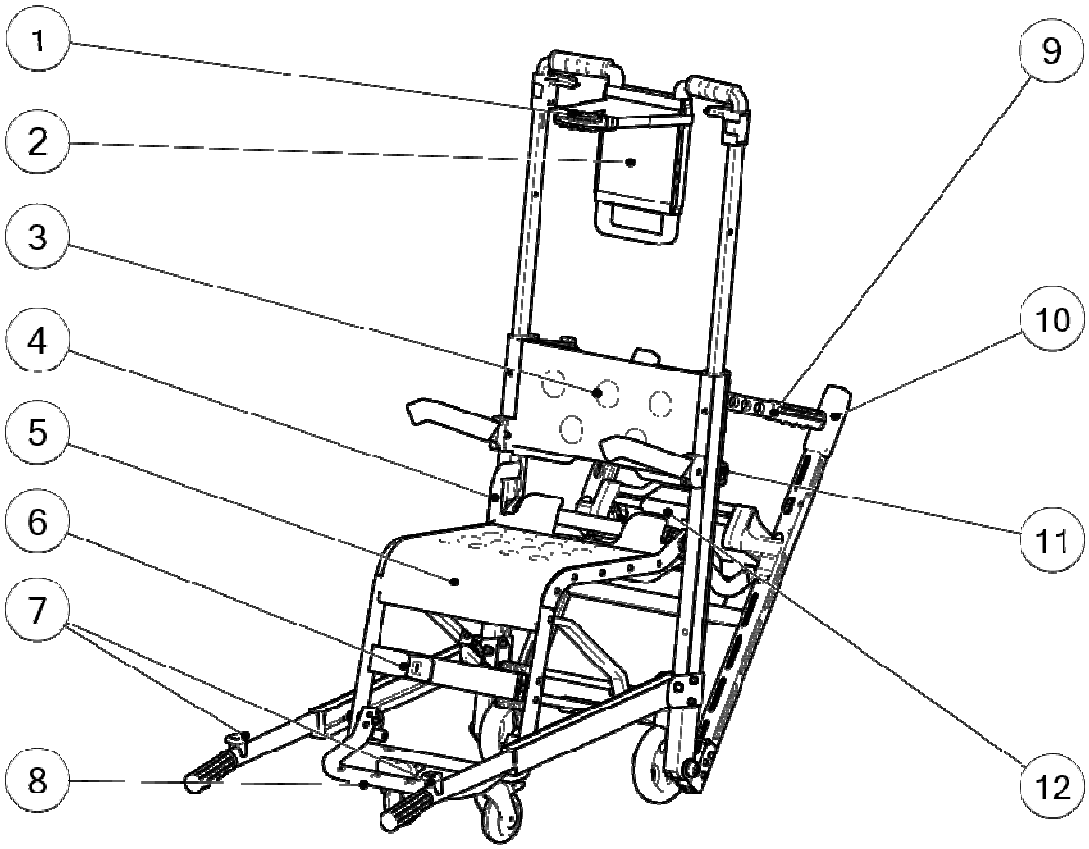


Fig. 1

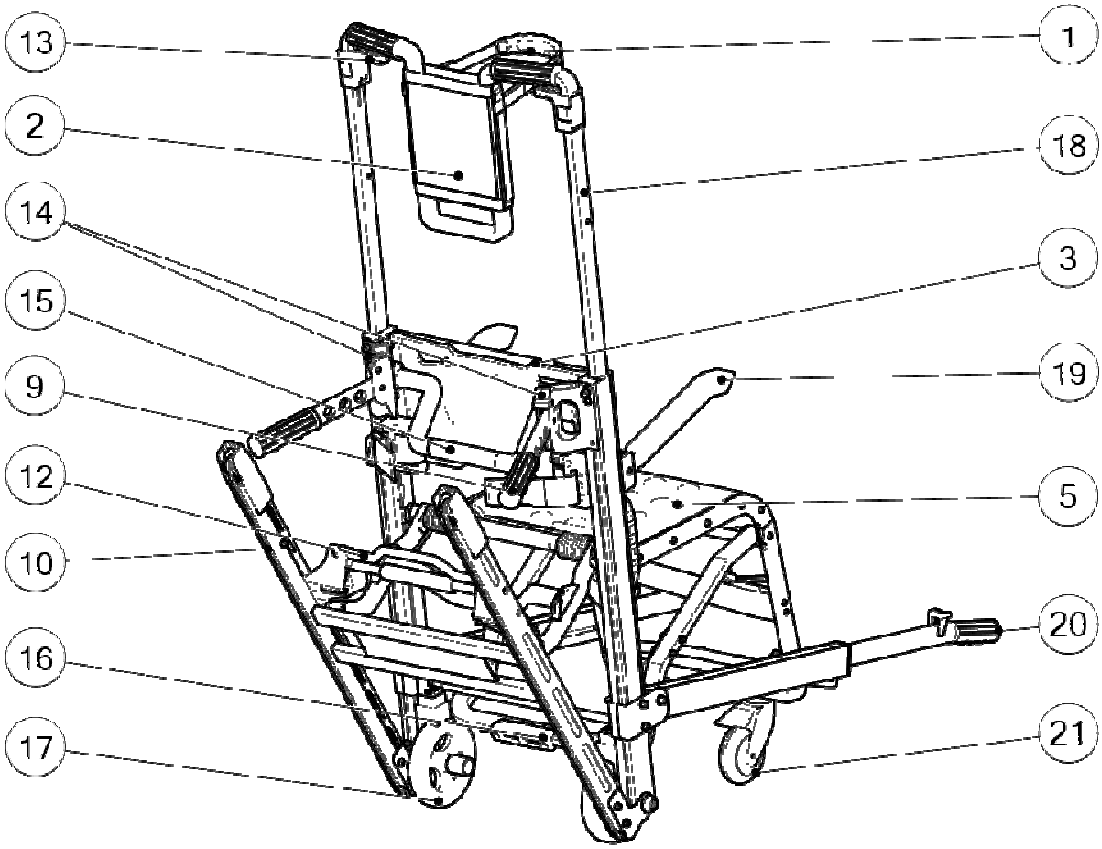
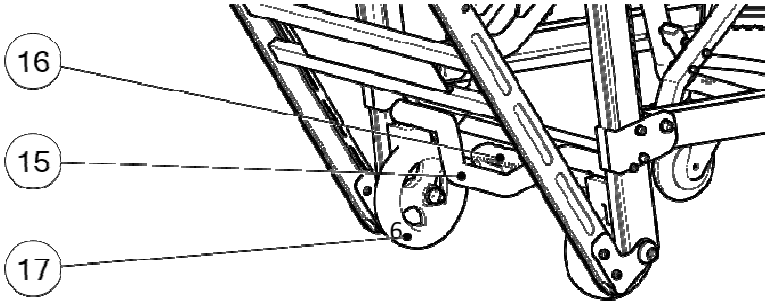


Fig. 2



3.3 Models

These basic models could be modified, with reference to codes and/or descriptions without any previous notification.

SK30000E EVA Evacuation chair E6
SK30003E EVA Evacuation chair E4
SK30004E EVA Evacuation chair E3
SK30005E EVA Evacuation chair E1
SK30006E EVA Evacuation chair E6 Max
SK30009E EVA Evacuation chair E5
SK30010E EVA Evacuation chair E7

3.4 Technical data

Technical characteristics	E6	E4	E3	E1	E5	E7
Height with open handle (mm)	1370	1370	/	/	1370	1370
Height closed (mm)	950	950	950	950	950	950
Width (mm)	530	530	530	530	530	530
Thickness closed (mm)	260	260	260	260	260	260
Length (mm)	900	900	900	900	900	900
Length with extended front and rear handles (mm)	1320	1320	1320	1320	1320	1320
Length with open slides and handles 8 mm)	1400	1400	/	/	1400	1400
Frame	Anodized and polished aluminium	Anodized and polished aluminium	Anodized and polished aluminium	Anodized and polished aluminium	Anodized and polished aluminium	Anodized and polished aluminium
Weight (kg)	19	16	15	12	19	17,5
Load capacity (kg)	170 (250 E6 Max)	170	170	170	170	170
Pivoting front wheels (mm)	n° 2 Ø 100	NO	n° 2 Ø 100	NO	n° 2 Ø 100	n° 2 Ø 100
Rear wheels (mm)	n° 2 Ø 150	n° 2 Ø 150	n° 2 Ø 150	n° 2 Ø 150	n° 2 Ø 150	n° 2 Ø 150

Characteristics of configurations	E6	E4	E3	E1	E5	E7
Central locking	✓	✓	✓	✓	✓	✓
Central brake for rear wheels	manual	pedal	manual	pedal	pedal	pedal
Slides with pre-tensioners	✓	✓	×	×	✓	✓
Sleds with ESC regulation	✓	×	×	×	×	×
Self-positioning front wheels	✓	×	✓	×	✓	✓
Integrated headrest	✓	✓	✓	×	✓	✓
Footrest	✓	×	✓	×	✓	✓
Belts with retractor	✓	×	✓	×	✓	×
Transport handle	✓	✓	✓	✓	✓	✓
Rear handles	✓	✓	✓	✓	✓	✓
Seat and backrest	Stabilizer (Spentex®)	Rigid (ABS)	Stabilizer (Spentex®)	Rigid (ABS)	Rigid (ABS)	Rigid (ABS)
Front armrests	✓	×	✓	×	✓	×
Reflective strip	✓	✓	✓	✓	✓	✓

3.5 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices

Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols for use in the medical device labels, labelling and information to be provided. Part 1: general requirements
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1/Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans

3.6 Environmental conditions

Functioning temperature: from -15 to +50 °C
Storage temperature: from -20 to +60 °C

4 OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself. Keep the original packaging for use in case of any further transport and for storage.
Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.
During storage, do not placed heavy materials over the device. The chair should not be considered and used as a shelf for any type of material.

4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. In particular, check:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of all nuts, bolts and screws
- Correct fixation of straps
- Correct fastening of straps
- State of use (moving parts, wheels, belts)
- Integrity of sewings and sheets
- No piping or metal sheet present bends or cracks
- The seat and the backrest do not present any lacerations and cuts
- Weldings are intact, without any cracks or breaks
- The seat belts, sheets, moving parts, wheels and handles are intact and functioning
- The wheels are fastened securely, are stable and running
- The wheels are free of debris
- The front-wheels are self-positioning (if equipped)
- The brake works correctly and is operated simultaneously
- The device opens and locks
- The device closes automatically
- The slides open
- The slides are automatically closed (if equipped)
- The belts of the sleds run and have always the correct tension for being used
- Functioning of springs
- The control system ESC can be selected (if equipped)

- The braking system is activated and deactivated
- The armrests lower and raise (if equipped)
- The carrying handle is securely attached to the device
- The seat belts for the immobilization of the patient are intact and functioning
- The lifting handles stretch and block
- The lifting handles open and close
- The front wheels are stable, turn, rotate and self-position around the pin (if equipped)
- The control handle extends and locks in any position (if equipped)
- The optional accessories are intact and functioning properly
- State of wear of the wheels and braking system
- State of wear of the slides and the sliding system with belt
- Presence of all labelling for proper use
- Integrity of components
- Integrity of handles (Are they torn or show signs of tearing? The seams are intact?)
- Lubrication of moving parts
- State of wear of the wheels and braking system
- The emergency vehicle is equipped with a Spencer fastening system dedicated to the device

If the above conditions are met, the device may be considered ready for use; otherwise you must immediately remove the device from service and contact the manufacturer.

4.3 Functioning

4.3.1 For opening the device

1. Stand behind the chair (fig. 3).
2. Insert the upper or pedal brake (fig. 4).
3. Separating the backrest from the seat. Once the chair is completely opened up to the stop, the locking mechanism will be inserted automatically (fig. 5).
4. Move the seat up; verify that the locking mechanism is activated. If the mechanism is functioning, the chair will not close.
5. Release the brake and proceed with other operations (fig. 6).

An unlocked chair may close during use, causing injury to the patient or operator. Before use, verify that the chair is always locked in the open position.

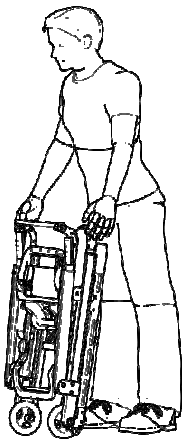


Fig. 3

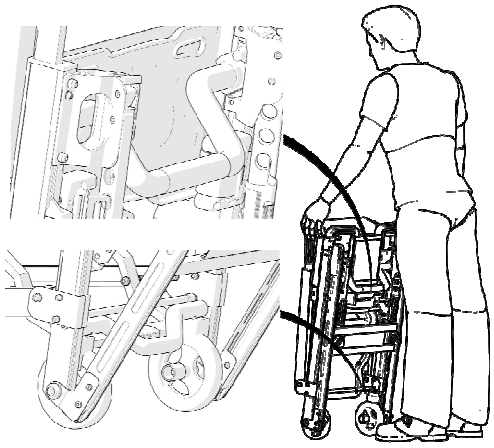


Fig. 4

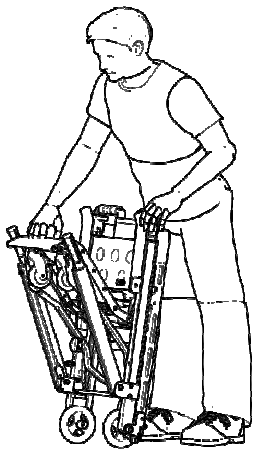


Fig. 5

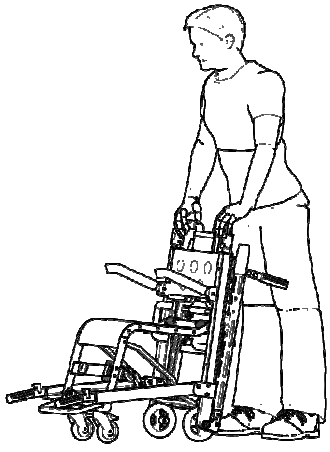


Fig. 6

4.3.2 For closing the device

1. Insert the brake (fig. 7). Fasten seat belts and fold them carefully as they may interfere during the closure of the chair. Close the telescopic front handles. If the chair is fitted with a head support strap, place it behind the structure of the chair. If the chair has armrests, fold them.
2. Stand behind the chair (fig. 8).

3. Tilt the chair a few degrees toward you, and verify that the self-positioning system of the front wheels, if any, function properly (fig. 8).
4. Press with the foot the red plastic base closer to the ground, and make sure the seat automatically reaches the backrest (fig. 8-9), when the closing of the device is exceptionally fast, accompany it with your free hand to avoid impacts to the structure of the device.

Make sure that the self-positioning system is working perfectly.
Verify that the chair once closed maintains this position, if this does not happen, it could cause injures to the operator.

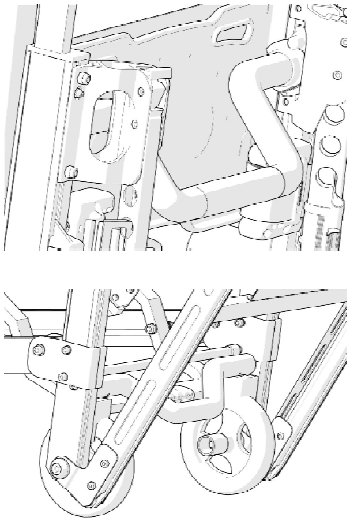
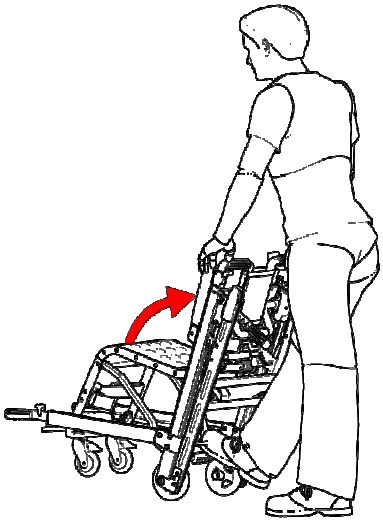


Fig. 7



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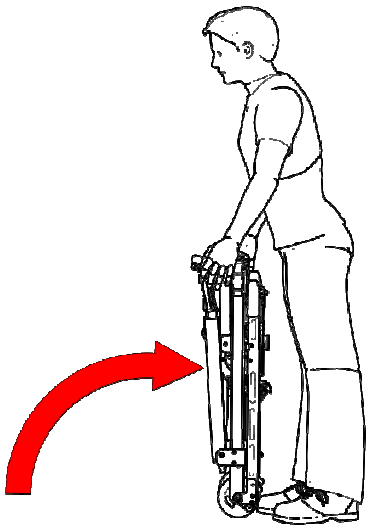


Fig. 9

4.3.3 Functioning of manual or pedal the brake

1. To activate the brake, move down the lever up to a full stop (fig. 10-12).
2. To release the brake, move the lever up to a full stop (fig. 11-13).

Insert the brake only when transferring patients to or from the chair or with empty chair.
<u>If the chair was moved with locking devices included, it might tip over causing injury to the patient or the operator and/or damage to the chair.</u>
The brake prevents that the empty seat can move when it is not monitored and as an aid during the transfer of the patient. The brake may not provide sufficient resistance on all surfaces or under load.
Apply the brakes in the phases of opening and closing of the chair.
Never leave the patient unassisted on the chair, because he could be injured. Keep the chair firmly if the patient is sitting.
Never use the brake on a chair with severely worn wheels. The use of the brake on a wheel with diameter of less than 150 mm could affect the sealing capability of the locking device and thereby cause possible injury to the patient or the operator and damage to the chair or other equipment.

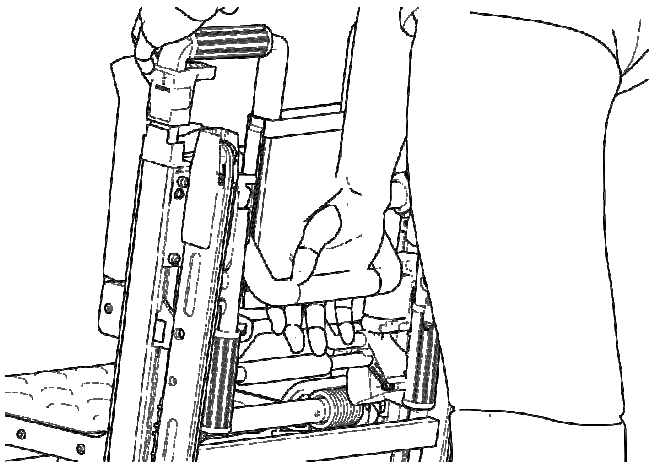


Fig. 10

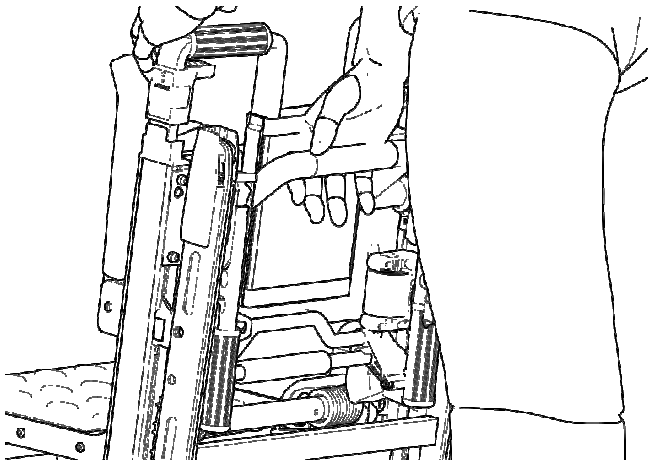


Fig. 11

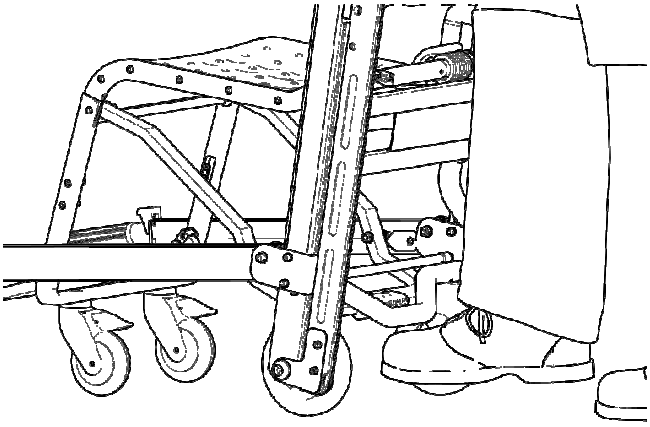


Fig. 12

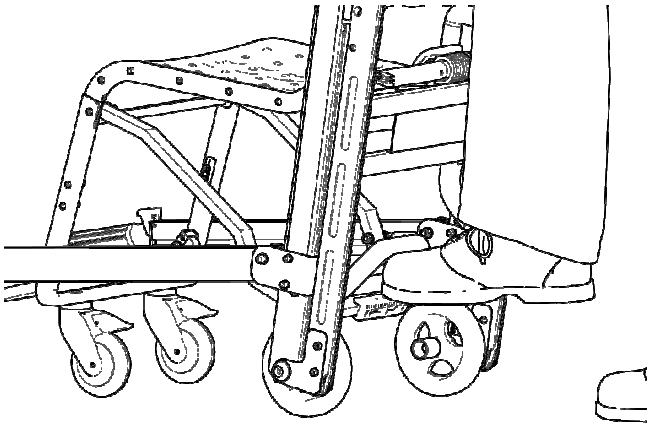


Fig. 13

4.3.4 For transferring the patient to the chair

1. Place the chair next to the patient.
2. Insert the brake to prevent the chair from moving.
3. Open seat belts.
4. Transfer the patient to the chair in accordance with procedures approved by the Emergency Medical Services.
5. Use all the belts to fasten the patient to the chair.
6. Before transporting the patient unlock the brake.

Do not use Eva chair in case of suspected suspects cervical or spinal traumas or fractures.

4.3.5 Use of safety belts

Always use safety belts to secure the patient to the chair. Otherwise the patient may fall off the chair and be injured.

Always secure the patient to the chair using all safety straps. For the version with roller the belt is already connected to the frame of the chair and already in the correct position.

To avoid damages to the belts and buckles, when the chair is not used with the patient, keep the straps fastened.

When the chair is put into service, open the seatbelts and keep them arranged on both sides of the chair until the patient is sitting. Lengthen the straps, fasten around the patient and shorten up to reach the fastening required to ensure the patient safely.

For belts with retractor it is necessary to remove them until they stop and then make the adjustment suitable to the patient.

To fasten the seat belt, push the male part in the female, until you hear a "click".

To unfasten the belt, press the tabs on the side of the buckle or the red button to release the buckle and pull the male part from the female.

While fixing the belt around the patient, always verify that the connection is firm and the excess part of the belt is not caught in the chair or hangs loose.

Check the belts before putting into operation, check carefully that the components are not bent or broken, the fabric belt is not torn or worn or frayed, etc. Immediately replace the belts which show signs of wear or malfunction.

4.3.6 Functioning of rear handles (if equipped)

For raising the rear handles:

1. The slides strips should be in the closed position (if present).
2. Lift handles completely (fig. 14).
3. Verify that the handles are locked in the open position.

The rear handles can be used only with the slides in the closed position.

The rear handles are designed only to lift the load, it is forbidden to apply loads down; failure to respect this warning may cause damage to the device, the operator and patient.

For lowering the rear handles:

1. To lower the lever to the left of the operator, unlock the red lever with the left hand (fig. 15).
2. Serve up the handle with the right hand to its complete closing (fig. 15).
3. To lower the lever to the right side of the operator, unlock the red lever with the right hand.
4. Serve up the handle with the left hand to its complete closing.

Verify that the handles are closed until complete stop, in order to avoid that the operator can bump them or be impeded.

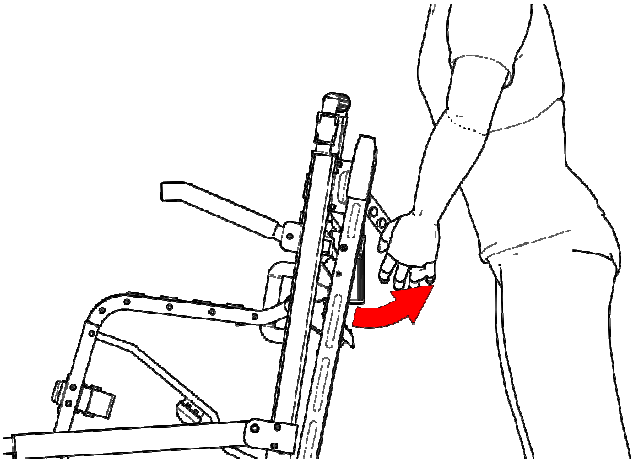


Fig. 14

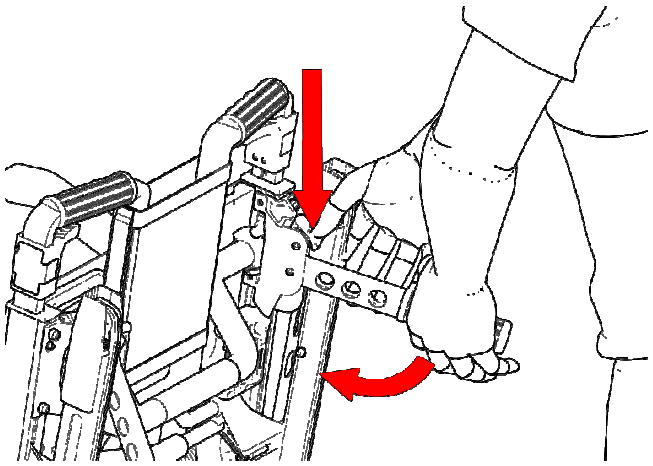


Fig. 15

4.3.7 Functioning of front handles

For extracting the front handles:

1. Stand in front of the device and grasp the handle you want to extract.
2. Press the red button next to the writing PUSH (fig. 16).
3. Pull the handle completely and release the button.
4. Make sure the handle is locked in the extended position.

Before lifting the device, ensure proper locking of the handle, the failure to observe this warning may cause damage to the device, the operator and patient.

For closing the front handles:

1. Stand in front of the device and grasp the handle you want to close.
2. Press the red button next to the writing PUSH (fig. 17).
3. Push the handle until it closes completely and release the button.
4. Make sure the handle is locked in the closed position.

Before closing or moving the device, verify the correct locking of the handle; failure to respect this warning may cause damage to the device, the operator and patient. The handle is equipped with a safety system, thanks to which the lever can not close, if not voluntarily. The safety system provides that when pushing in the direction of closing of the handle, if the operator inadvertently presses the release button, this does not intervene. Preserving the security characteristics of the device.

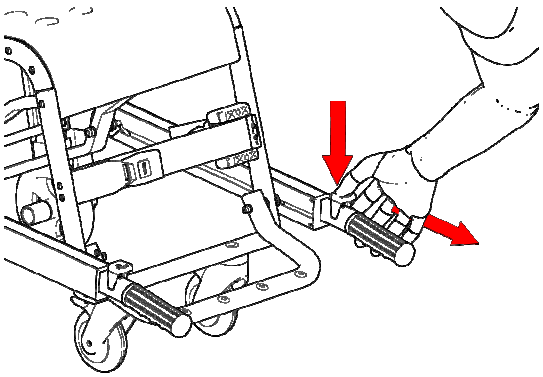


Fig. 16

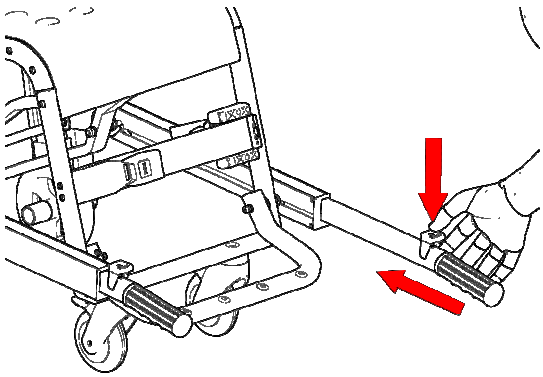


Fig. 17

4.3.8 Functioning of lift bar (if equipped)

For opening the lift bar:

1. Take position in the rear part of the device.
2. Grasp the lift bar with both hands near specific rubber parts.

3. Press with your fingers the two red levers upwards (fig. 18).
4. Pull up to full opening the lift bar and release the buttons.
5. Verify that the lift bar is locked in the extended position.

The use of the lift bar is only intended for the phases of descent with the slides open.
Before moving the device, check the proper locking of the lift bar, the failure to respect this warning may cause damage to the device, the operator and patient.

For closing the lift bar:
1. Take position in the rear part of the device.
2. Grasp the lift bar with both hands near specific rubber parts (fig. 19).
3. Press with your fingers the two red levers upwards.
4. Pull down to full closing the lift bar and release the buttons.
5. Verify that the lift bar is locked in the closed position.

Before moving the device, check the proper locking of the lift bar, the failure to respect this warning may cause damage to the device, the operator and patient.

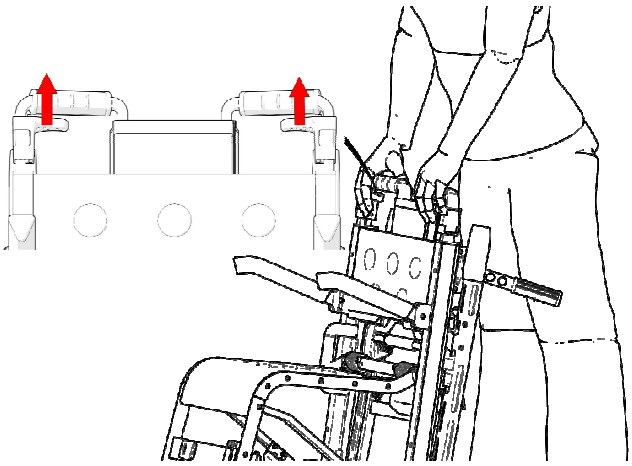


Fig. 18

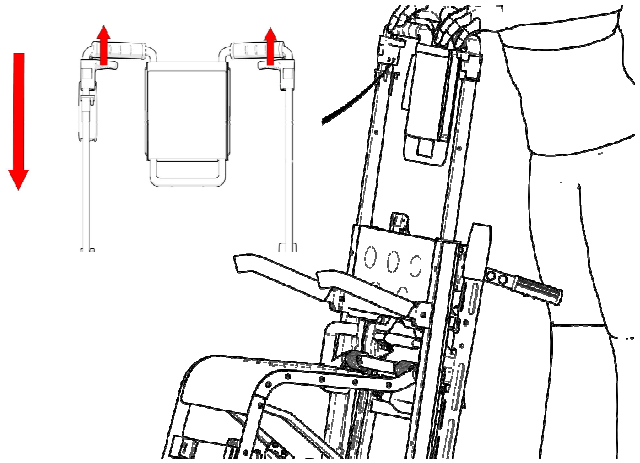


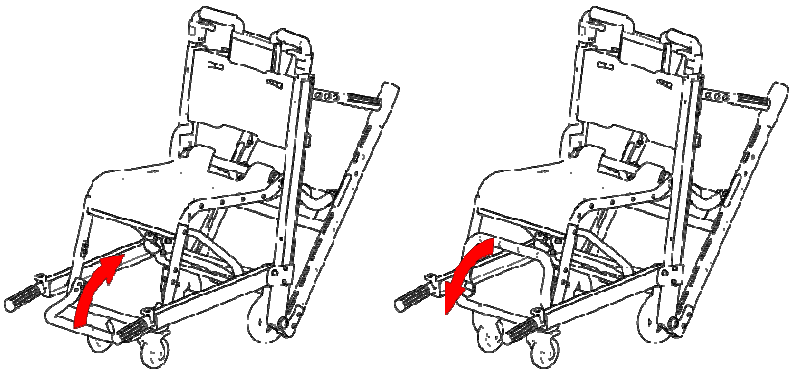
Fig. 19

4.3.9 Functioning of footrest (if equipped)

For opening the footrest:
1. Carry out the operations for the opening of the chair.
2. Take the footrest and recline it until complete opening towards the front of the chair (fig. 20).
3. Make sure that the footrest is properly reclined.

Before transferring the patient on the chair and using the footrest, make sure it is properly secured to the structure of the chair.
The footrest is not designed to support the total weight of the patient, but only to give greater comfort when he is sitting on the chair, the failure to do so may cause damage to the device, the operator and patient.

For closing the footrest:
1. With the chair open, take the footrest and recline it towards the rear part of the chair, up to its complete closure (fig. 21).
2. In the case it is desired to close the chair, perform all the operations explained above in this manual, in this case the footrest has a mechanism that allows to automatically close again.



3. Before using or storing the chair, make sure that the footrest is properly closed.

Fig. 20

Fig. 21

4.3.10 Functioning of armrests (if equipped)

For opening the armrests:

1 Carry out the operations for the opening of the chair.
2 Take the armrests and recline them until complete opening towards the front of the chair (fig. 22).
3 Make sure the armrests are properly reclined.

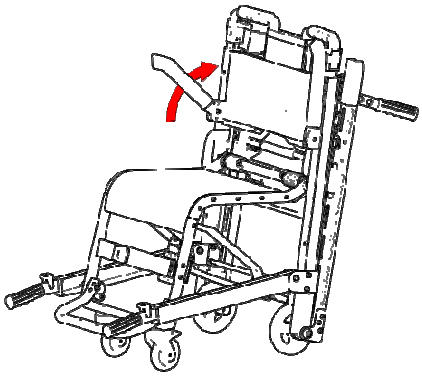


Fig. 22

Before transferring the patient on the chair and using the armrests, make sure they are properly secured to the structure of the chair.
The armrests are not designed to support the total weight of the patient, but only to give greater comfort when he is sitting on the chair, the failure to do so may cause damage to the device, the operator and patient.

For closing the armrests:

1. With the chair open, take the armrests and recline them towards the rear part of the chair, up to their complete closure.
2. Perform the same manoeuvres before closing of the device.

4.3.11 Functioning of the sliding system (if equipped)

For opening the slides:

1. Carry out the operations for opening the chair.
2. Brake the chair following the procedures described above (paragraph 4.3.3).
3. Stand in the rear part and lift with your finger the red button (par. 3.2 n° 11), at the left of the chair, between the supporting pipe of the chair and the slide.
4. **For models equipped with variable geometry**, maintaining the red button activated, with the other hand hold the tube labelled with the adhesive ACTIVATE SLIDE. Once held the tube identified by the adhesive, lift upwards until intercepting the first fixing hole of the adjustment system ESC (fig. 23).
   The regulation of the ESC (Eva Scrolling Control) system is made by the operator according to the following features of the situation that arises:
   a. Physical characteristics of operators
   b. Inclination angle of the stairs
   c. Weight of transported patient
   Range of adjustments ESC system:
   GREEN: standard inclination for use in all permitted conditions in compliance with all the warnings given in the user's manual of the device.
   YELLOW: reduction of the angle of inclination compared to the green position, with consequent increase in the sliding of the chair.
   RED: reduction of the angle of inclination compared to the yellow position, with a consequent increase in the sliding of the chair.
   The adjustment is made by holding with the left or right hand the tube that is labelled with the adhesive ACTIVATE SLIDE, and pressing with the opposite hand towards the top the red plastic tube. Raising or lowering the tube ACTIVATE SLIDE it is possible to select the desired position.
   For versions with fixed position lift the red button (par. 3.2 n° 11) the slide opens automatically.

Before use of the device verify that you have correctly selected the position of the slides and the full opening.

For closing the sliding system:

1. Brake the chair following the procedures described above.
2. Check that the rear handles are properly closed.
3. **For models equipped with variable geometry** take with your left or right hand the tube indicated with the adhesive ACTIVATE SLIDE and with the opposite hand push up the red plastic tube (fig. 24). Accompany the slide until completely closing.
4. **For versions with fixed position** grab the tube indicated with the adhesive ACTIVATE SLIDE, press it down, and with your free hand accompany the slide until it is completely closed.

5. Make sure that the slide is properly locked.

Be careful during the closing phase of the slide not to place your hands between the fixed structure of the chair and the slides. Failure to comply with this warning may result in damage to the device, the operator and the patient.

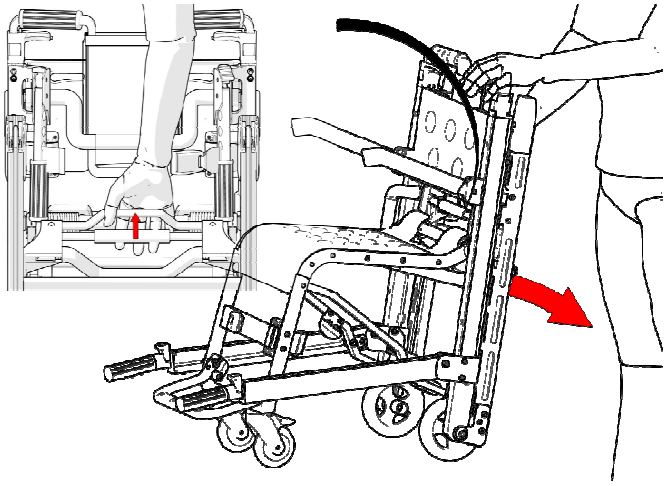


Fig. 23

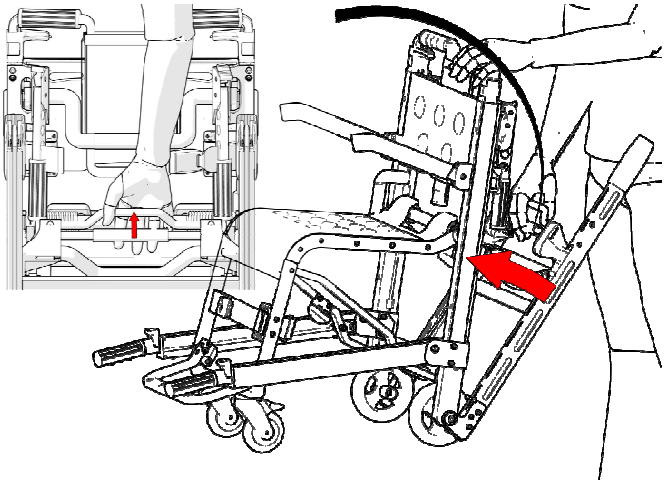


Fig. 24

4.3.12 Functioning of self-positioning front wheels (if equipped)

1. The front wheels without load or in the raised position from the ground, are self-positioning in order to facilitate the automatic closing of the chair.
2. The wheels in the presence of the load on the device are self-positioning in the direction of travel.

To handle the chair in the open position and without patient or load, hold raised the front wheels and slide the chair only on the rear wheels, to obtain a better smoothness of the device.

Check that the wheels are always self-positioning in such a way that the automatic closure is fully operational.

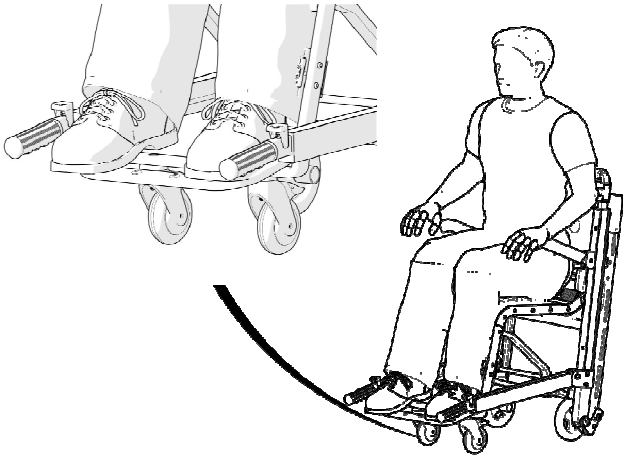


Fig. 25

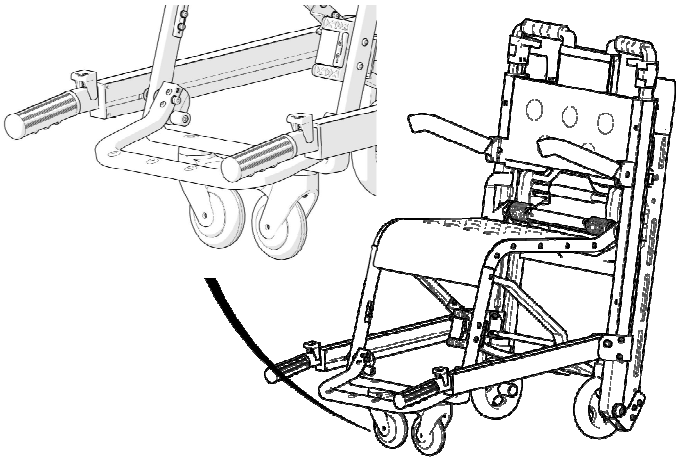


Fig. 26

4.3.13 Functioning of head support (if equipped)

It's better not to use the Eva chair in case of suspected cervical traumas, spinal damages or fractures.

Before using the head support, extend the handle as specified in paragraph 4.3.8.

Fix the head support around the head of the patient, in the desired tension to hold the head well stabilized. When the straps are not in use, keep them stored inside the headrest made of PVC

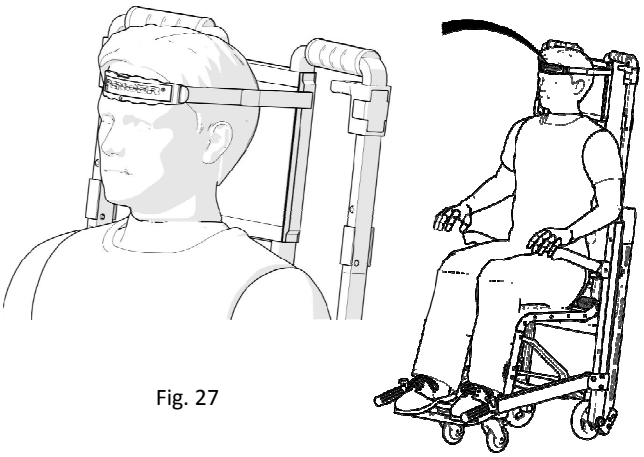


Fig. 27

4.3.14 Patient transport on flat surfaces

TECHNIQUES FOR CORRECT LIFTING

When lifting the Eva chair with the patient, you must consider five guidelines:
1. Keep your hands close to your body.
2. Keep your back straight.
3. Coordinate your movements with those of the other operator and lift your legs.
4. Avoid twisting.
5. Use the Eva chair as described in this manual.

For moving the chair on a flat surface, push and guide the chair from behind, using the lift bar in the closed position (see paragraph 4.3.8) or fixed lift bar.
If obstructed, lift or turn the chair through the lifting handles on the head side and foot side.

Patient loading procedures for extremely heavy patients, operations in rough terrain and in particular situations more operators may be needed (not only two as in normal conditions).
The wheels are not suitable for all surfaces. Be always very careful.

4.3.15 Patient transport during the descent of the stairs

To avoid any risk for the safety of the patient, during the transport on the stairs, it is necessary that at least two operators are employed. In the event that more people are required to ensure safe operation of the chair, please see the section on USE OF ADDITIONAL SERVICE to locate the right position that every operator must occupy.
To avoid injury, before transporting the patient, verify that the bar and the slides are locked into place.
To avoid injury, before lifting the chair through the lifting handles, check that they are always locked in their position.

After immobilizing the patient to the chair, perform the following operations:

1. Bring the chair next to the stairs and align it perpendicularly to the edge of the first step.
2. Operator foot side: pull the lifting handles at the foot end by pressing the red release buttons and polling the handles until they stop. Release the buttons and verify that the handles are securely locked in the correct position.
3. Operator head side: pull the lift bar with both hands, and then open the slides.
4. During the descent of the stairs operators are facing each other.
5. Operator head side: tilt the chair back far enough to permit the slides to touch the floor.
6. Both operators: maintaining the same angle of inclination, bring the chair to the edge of the stairs, so as to enable the slides to position themselves on the first step.
7. Both operators: slide the chair until the slides are levelled with the edges of 3 steps.
8. Operator head side: in order to avoid that the chair swings forward as it slides down the stairs, exert a slight downward pressure on the lift bar while the operator at the foot end exerts a slight upward pressure on the lifting handles at the foot side.
9. If during the descent of the stairs an operator wants to stop or rest, tilt the chair forward, just enough to allow the rear wheels to lean on the corner of the step. To resume the descent from the rest position, the operator at the head end exerts a light pressure down on the rear handle while the operator at the foot end exerts a slight upward pressure, so as to tilt the chair back and engage the slides.
10. Operator foot side: when the slides reach the last step, release the front handles.
11. Operator head side: tilt the chair forward until all four wheels are on the floor, move the chair.
12. Fold down the slides and the front handles as specified in this user's manual.

The sliding system may not always work in the same way on any type of stairs and in all environmental conditions. Depending on the conditions of use, you may meet sometimes different strength.
Prevent the presence of debris or other type of obstructions inside the slide rails.
Water, ice and debris on the stairs can cause loss of balance to the operator and jeopardizing the proper functioning of the chair. To avoid injury, free the way from obstacles or consider an alternative route.
Condensation, water, ice and/or accumulation of dust on the chair are factors that can affect the operation, making it unpredictable, this may cause a sudden alteration of the weight that operators have to bear. To avoid the risk of accidents, and to allow the proper functioning of the chair, make sure that the straps are clean and dry prior to transport of the patient.
To prevent injuries, the operators and/or patient, the operators should never carry patients weighing greater than the maximum weight recommended for safe lifting.

4.3.16 Patient transport during stair climbing

To avoid any risk to the safety of the patient, during transport on the stairs it is necessary that at least two operators are employed. In the event that more people are required to ensure safe operation of the chairs, please refer to the section about USE OF ADDITIONAL ASSISTANCE to find the right position that each operator must occupy.
To avoid injury, before lifting the chair with the lifting handles, make sure that they are always locked in place.

1. Bring the chair at the end of the stairs with the back of the patient facing the stairs.
2. Operator foot side: Open the lifting handles at foot end.
3. Operator head end: Open the handles to lift the head end.
4. The operator at the foot side is facing the stairs. The operator at the head side may be towards the patient, for a better control of the patient, or forwards, for a better view of the stairs and to be able to cope better maneuvering in case of obstacles.
5. Both operators using the handles at the head and foot end, lift the chair at the same time adhering to proper lifting techniques. Carry the chair slowly climbing the stairs without any obstruction.

Even if the operator placed at the head side can be turned in both directions, while lifting and transporting the chair, you must follow all protocols for chairs transport.

USE OF ADDITIONAL ASSISTANCE

To avoid any risk to the safety of the patient, during transport on the stairs it is necessary that at least two operators are employed. In the event that more people are required to ensure safe operation of the chairs, please refer to the section about USE OF ADDITIONAL ASSISTANCE to find the right position that each operator must occupy.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The device doesn't release from the closed or open position during functioning or closing phase	The functioning geometry is compromised or seized; the safety devices have not been removed	After performing adequate lubrication, check if the problem persists. If so put the device out of service and contact the service centre.
Difficulties in the extraction and insertion of telescopic handles or rear handles	Sediments in the slides area or yielding of the aluminium profile	Carry out thorough cleaning. If the problem persists, do not use the device for handling involving the ascent of the stairs and contact the service centre.
Injuries to the structure	Misuse and inadequately trained staff	Put the device out of service and contact the service centre

5 MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.
The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

The exposed metal parts are usually treated and/or painted in order to increase their resistance.
Clean the exposed parts with water and delicate soap then dry with a soft cloth; never use solvents or stain removers. If disinfection is required, use a quaternary or phenolic disinfectant diluted in the proportions specified by the manufacturer that does not have solvent or corrosive action on the materials.
Do not use pressure washing, steam or ultrasonic. Rinse thoroughly with warm water, the water temperature must not exceed 40° C, verifying to have eliminated all traces of detergent, which could be degrading or compromising the integrity and durability of the device.
The water pressure must not exceed 3 bar. Indeed, water penetrates the joints and removes the oil, creating the risk of corrosion of components.
Dry accurately with a soft cloth and taking care to avoid water going inside the chair; do not use flames or other sources of direct heat.

Failure to comply with instructions may void the warranty.

5.2 Maintenance

Establish a maintenance program and periodic testing, identifying a reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in the user's manual.

Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or manufacturer if requested.

With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
Both public and private operators are obliged to inform the manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users.

5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the manufacturer to maintain post sales records and traceability of the appliance if requested.

During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.

Checks to be carried out before and after each use, and at least once a month, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of all nuts, bolts and screws
- Correct fixation of straps
- Correct fastening of straps
- State of use (moving parts, wheels, belts)
- Integrity of sewings and sheets
- No piping or metal sheet present bends or cracks
- The seat and the backrest do not present any lacerations and cuts
- Weldings are intact, without any cracks or breaks
- The seat belts, sheets, moving parts, wheels and handles are intact and functioning
- The wheels are fastened securely, are stable and running
- The wheels are free of debris
- The front-wheels are self-positioning (if equipped)
- The brake works correctly and is operated simultaneously
- The device opens and locks
- The device closes automatically
- The slides open
- The slides are automatically closed (if equipped)
- The belts of the sleds run and have always the correct tension for being used
- Functioning of springs
- The control system ESC can be selected (if equipped)
- The braking system is activated and deactivated
- The armrests lower and raise (if equipped)
- The carrying handle is securely attached to the device

- The seat belts for the immobilization of the patient are intact and functioning
- The lifting handles stretch and block
- The lifting handles open and close
- The front wheels are stable, turn, rotate and self-position around the pin (if equipped)
- The control handle extends and locks in any position (if equipped)
- The optional accessories are intact and functioning properly
- State of wear of the wheels and braking system
- State of wear of the slides and the sliding system with belt
- Presence of all labelling for proper use
- Integrity of components
- Integrity of handles (Are they torn or show signs of tearing? The seams are intact?)
- Lubrication of moving parts
- State of wear of the wheels and braking system

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage.
Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

The person responsible for every day maintenance can substitute the spare parts indicated on paragraph “Spare Parts”, only if authorized by the manufacturer or by a centre authorised by Spencer.

Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise we will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the manufacturer or by one of the manufacturer's authorised service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/CEE.

5.2.2 Periodic maintenance

The device must be serviced by the manufacturer or by an authorised centre every year.
If the correct revision is not carried out, the CE branding will no longer be considered valid as it will no longer be compliant with the 93/42/CEE Directive for Medical Devices and therefore there is the possibility that it is no longer compliant with the safety standards declared by the manufacturer at time of purchase.
Spencer Italia S.r.l. will take no responsibility the incorrect functioning or any damage caused by a device that has not undergone regular revision.
For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

5.2.3 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.
For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.
The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer. Straps and seat and backrest sheets have an average life span of 2 years.
Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the manufacturer or by one of the manufacturer's Authorised Service centres, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

SK30001E	Hook E-Max 10 G
SK30002E	Hook E-Max 20 G
Ask Spencer	Telescopic IV pole
Ask Spencer	Tank holder fixation system 2 L

6.2 Spare parts

SK30109C	Seat sheet in Spentex®
SK30110F	Backrest sheet in Spentex®
SK30113E	Rigid seat ABS
SK30114E	Rigid backrest ABS
SK30100C	Reflective labels kit
SK30116C	Headrest
SK30117C	Retractable strap with male hook
SK30118C	Upper retractable strap with female hook
SK30119C	Armrests cover

ATTACHMENT A – TRAINING REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
Keep this document at least 10 years from the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.
Perform the required maintenance and to respect the life span of the device, as indicated by the manufacturer in the user's manual.

Code and description of the device	
Purchase date	
Lot (LOT) or serial number (SN)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance/ check/ extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (operator/ authorized centre/ manufacturer)

Warning
The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.
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